UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, AND WASHINGTON, *ex rel.* ROBERTA POWELL, Plaintiffs, -v.- MEDTRONIC, INC., MEDTRONIC USA, INC., MEDTRONIC MINIMED, INC., and MINIMED DISTRIBUTION CORP., Defendants.	18 Civ. 1628 (KPF) **OPINION AND ORDER**

KATHERINE POLK FAILLA, District Judge:

On behalf of the United States of America and twenty-six states, Relator Roberta Powell ("Relator") filed this *qui tam* action alleging that Medtronic, Inc., Medtronic USA, Inc., Medtronic MiniMed, Inc., and MiniMed Distribution Corp. (collectively, "Medtronic" or "Defendants") engaged in a fraudulent scheme to encourage customers to reuse a component piece of Defendants' now-discontinued iPro2 Continuous Glucose Monitoring system (the "iPro2 System") on multiple patients — contrary to its Food and Drug Administration (the "FDA") label — thereby causing healthcare providers to submit false reimbursement claims to federal and state healthcare programs, in violation of the federal False Claims Act (the "FCA"), 31 U.S.C. §§ 3729-3733, and twenty-

six named state-law equivalents. Defendants seek to dismiss the Second Amended Complaint, the operative pleading in this action, for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the Court grants Defendants' motion.

BACKGROUND[1]

A. Factual Background

1. The Parties and the iPro2 System

Medtronic supplies diabetes-related medical devices, including at one time the iPro2 System. (SAC ¶ 14). Medtronic marketed the iPro2 System to customers around the world. (*Id.* ¶ 147). Relator Roberta Powell identifies herself as a "diabetes educator" and "clinician" who, in September 2017, underwent Medtronic's training program to become a certified iPro2 System trainer. (*Id.* ¶¶ 7-9).

The iPro2 System is a Continuous Glucose Monitoring ("CGM") system that continuously records interstitial glucose levels in persons with type 1 and type 2 diabetes. (SAC ¶ 49). CGMs allow physicians and patients to identify fluctuations and trends in a patient's glucose levels that may go undetected

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[1] This Opinion draws its facts from the Second Amended Complaint (the "SAC" (Dkt. #65)), the well-pleaded allegations of which are taken as true for purposes of this Opinion. *See Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009).

For ease of reference, the Court refers to Defendants' memorandum of law in support of their motion to dismiss as "Def. Br." (Dkt. #71); to Relator's memorandum of law in opposition to Defendants' motion as "Pl. Opp." (Dkt. #76); to Defendants' reply memorandum of law as "Def. Reply" (Dkt. #81); and to Relator's sur-reply memorandum of law as "Pl. Sur-Reply" (Dkt. #82).

with intermittent blood sugar tests. (*Id.*).[2] CGMs are Class III medical devices requiring FDA premarket approval pursuant to the Food Drug and Cosmetic Act, 21 U.S.C. §§ 351-360 (the "FDCA"). (*Id.*).

The iPro2 System employs a sensor (the "Sensor") that is inserted subcutaneously into the patient's abdomen. (SAC ¶ 50). A rigid "introducer needle," which is part of the Sensor, aids in the insertion of the Sensor into the subcutaneous tissue. (Def. Br., Ex. A ("iPro2 User Guide") at 1-127). A physician may elect to use a sensor inserter device called a "Serter," to guide the introducer needle to the targeted area of tissue. (*Id.* at 1-120). The use of a Serter is optional. (*Id.*, Ex. B ("FDA Summary of Safety and Effectiveness Data") at 3). While the Serter does make contact with the patient's skin, unlike the Sensor, it is not inserted into the patient's skin. (*See generally id.*, Ex. C ("Serter User Guide"); *see also* SAC ¶ 57). Following the insertion process, the Sensor is attached to the skin using an adhesive patch and connected to an electronic transmitter device that records interstitial glucose readings continuously during the period that the patient wears the device. (SAC ¶ 50).

In 2016, the iPro2 System received premarket approval from the FDA. (SAC ¶ 55). According to Medtronic's FDA-approved label for the iPro2 System, the iPro2 System is intended for multiple-patient use. (*See* iPro2 User Guide at 1-49, 1-60 ("The iPro2 is intended for multiple patient use[.]")). However, the FDA has cleared the Serter component of the iPro2 System as a "single-patient

[2] In this Opinion, the Court uses the term "physicians" broadly to refer to healthcare providers.

use device," stating that it can be used on the same patient for up to "600 … insertion uses." (SAC ¶ 58; Serter User Guide at 10). In other words, while the Serter can be used repeatedly on the same individual, it is not approved to be used on multiple patients. Relator alleges that reusing the Serter on multiple patients poses a significant risk of contamination and infection. (SAC ¶ 57).

Unlike Serters, Sensors are designated as single-*use* devices, meaning that a Sensor should only be inserted into the patient once and then discarded after use. (*See* iPro2 User Guide at 1-127).

2. Healthcare Plan Reimbursement of the iPro2 System

Federal healthcare payors reimburse healthcare providers' use of CGMs, including the iPro2 System, under two Current Procedural Terminology ("CPT") Codes, which identify the services rendered for which reimbursement is sought. (SAC ¶ 52). The first is CPT Code 95250, the technical component, which is used to reimburse healthcare providers for the costs related to physician-provided equipment. (*Id.*). The second is CPT Code 95251, the professional component, which is used to reimburse physicians for their services — here, for the analysis, interpretation, and reporting of the glucose monitoring data captured by the device. (*Id.*). Service providers are reimbursed at a set rate under these CPT codes, regardless of the specific equipment used. In other words, a physician administering a CGM to a patient will be reimbursed the same amount under these CPT codes regardless of whether she uses a Serter, some other guiding instrument, or no guiding instrument at all. Physicians will also be reimbursed the same amount regardless of the brand or

manufacturer of the CGM device (*i.e.*, Medtronic's iPro2 System or some other brand device). (*Id.* ¶¶ 31, 146). From these facts, Relator reasons that providers can increase their profits by choosing less expensive CGMs. (*Id.* ¶¶ 52-54, 61-62).

3. The CGM Market and Medtronic

Relator alleges that, after receiving FDA approval for the iPro2 System in 2016, Medtronic experienced significant challenges from its main competitors, which manufactured similar CGM products at a lower cost. (SAC ¶ 62). To make the iPro2 System less expensive for providers, Medtronic resorted to promoting the Serter to physicians as a device they could reuse to guide the insertion of the Sensor on multiple patients, in violation of the FDA label. (*Id.*). At all relevant times, Medtronic sold each Sensor for approximately $60 and each Serter for approximately $30. (*Id.* ¶ 56). Thus, a physician who used the iPro2 System according to the FDA label would incur $90 in costs for a new Sensor and Serter for each new patient procedure. Conversely, a physician who reused a Serter to insert a Sensor could save $30. (*Id.* ¶¶ 63-64).

According to Relator, to implement this strategy, Medtronic (i) instructed its sales staff, product trainers, and clinical managers to train providers to reuse the Serter on multiple patients and simply wipe the Serter with a "CaviWipe" — a medical-grade wipe — between patients in order to save costs (SAC ¶ 65); (ii) changed its purchasing system to promote and incentivize Serter reuse (*id.* ¶¶ 107-113); and (iii) introduced pricing incentives to further promote the practice (*id.* ¶¶ 110-111). Relator also asserts that Medtronic staff

"in multiple departments and at multiple levels knew about and furthered this systemic conduct," including Medtronic's then-Principal Clinical Sales Manager (and current Director of Medical Affairs), the company's sales team, and the company's contracted clinical trainers. (*Id.* ¶ 83).

Prior to encouraging Serter reuse, Medtronic never conducted any testing to determine if Serter reuse on multiple patients was safe. (SAC ¶¶ 68-73, 82). It also never sought approval from the FDA to market the Serter as a multi-patient-use device. (*Id.* ¶¶ 70-71). Indeed, Relator alleges that Medtronic had "actual knowledge," from its own internal testing, that reusing the Serter between patients without a comprehensive disinfection process — soaking the Serter for at least 30 minutes in bleach or soap — exposed patients to infection risk, but never shared these findings with customers. (*Id.* ¶¶ 74-78, 158).

Relator argues that because patients could be exposed to an unnecessary risk of infection when a Serter is reused on multiple patients (as compared to when the same procedure is performed with a new Serter), the reuse of the Serter component (i) renders the iPro2 System "adulterated" (SAC ¶ 127), and (ii) renders the corresponding care not medically "reasonable and necessary," and thus not reimbursable by federal healthcare programs (*id.* ¶ 129). Accordingly, Relator asserts that Medtronic knowingly caused Medicare, and other federal healthcare programs, to pay millions of dollars in false claims for iPro2 Systems.

B. Procedural Background

On February 22, 2018, Relator filed her original Complaint under seal. The United States of America investigated Relator's allegations and, on April 4, 2023, declined to intervene, as did the twenty-six named states. (*See* Government's Notice of Election to Decline Intervention (Dkt. #18); Plaintiff States' Notice of Election to Decline Intervention (Dkt. #19)). On April 4, 2023, the Court unsealed the original Complaint. (Dkt. #15 (unsealing order), #17 (Complaint)).

On August 14, 2023, Defendants filed a letter motion in anticipation of their motion to dismiss that outlined purported deficiencies in Relator's initial Complaint. (Dkt. #48). Following Defendants' filing of the letter motion, on September 18, 2023, Relator filed her First Amended Complaint. (Dkt. #56).

On October 16, 2023, Defendants, once again, filed a letter motion to dismiss the First Amended Complaint (Dkt. #59), which motion Relator opposed (Dkt. #60). On November 21, 2023, the Court held a pre-motion conference to discuss the issues raised by both parties. (*See* November 21, 2023 Minute Entry; Dkt. #66 (transcript)). During the conference, Relator indicated that she might wish to file a second amended complaint. (*Id.*).

On January 12, 2024, Relator filed the Second Amended Complaint that is the subject of the instant motion to dismiss. (Dkt. #65). In accordance with a briefing schedule endorsed by the Court, Defendants filed their motion to dismiss on February 23, 2024. (Dkt. #70-71). After requesting an extension of time, Relator filed her opposition to Defendants' motion on April 5, 2024. (Dkt.

#76). Defendants filed their reply in further support of their motion to dismiss on May 3, 2024. (Dkt. #81). Finally, Relator filed a sur-reply in further opposition to Defendants' motion on May 17, 2024. (Dkt. #82).

DISCUSSION

A. Applicable Law

1. Motions to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)

Under Rule 12(b)(6), a defendant may seek dismissal of a plaintiff's action for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When considering a motion to dismiss under Rule 12(b)(6), a court must "draw all reasonable inferences in [p]laintiff['s] favor, 'assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief.'" *Faber* v. *Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (quoting *Selevan* v. *N.Y. Thruway Auth.*, 584 F.3d 82, 88 (2d Cir. 2009)); *see also Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009).

A plaintiff is entitled to relief if the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 570 (2007); *see also In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007) ("While *Twombly* does not require heightened fact pleading of specifics, it does require enough facts to 'nudge [plaintiff's] claims across the line from conceivable to plausible.'" (quoting *Twombly*, 550 U.S. at 570)). Moreover, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and

plausibility of entitlement to relief.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

A court adjudicating a motion to dismiss under Rule 12(b)(6) "may review only a narrow universe of materials." *Goel* v. *Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). This narrow universe includes "the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *United States ex rel. Foreman* v. *AECOM*, 19 F.4th 85, 106 (2d Cir. 2021) (citation omitted). "Where a document is not incorporated by reference, the court may never[the]less consider it where the complaint 'relies heavily upon its terms and effect,' thereby rendering the document 'integral' to the complaint." *Id.* (citation omitted); *see also Goel*, 820 F.3d at 559 ("A document is integral to the complaint where the complaint relies heavily upon its terms and effect." (internal quotation marks and citations omitted)).

2. Pleading Sufficiency Under Federal Rule of Civil Procedure 8

Rule 8(a) of the Federal Rules of Civil Procedure requires that a pleading include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint "satisfies the requirements of Rule 8(a) [when] it gives [each defendant] fair notice of the basis for [the plaintiff's] claims." *Swierkiewicz* v. *Sorema N.A.*, 534 U.S. 506, 514 (2002). The Rule "does not countenance pleadings that are conclusory; it requires factual allegations that are sufficient to 'give the defendant fair notice of what the … claim is and the grounds upon which it rests.'" *Anderson News,*

L.L.C. v. *Am. Media, Inc.*, 680 F.3d 162, 182 (2d Cir. 2012) (quoting *Twombly*, 550 U.S. at 555). "[T]he principal function of pleadings under the Federal Rules is to give the adverse party fair notice of the claim asserted so as to enable him to answer and prepare for trial." *Salahuddin* v. *Cuomo*, 861 F.2d 40, 42 (2d Cir. 1988).

The Second Circuit has noted the "distinction between the notice requirements of Rule 8(a) and the requirement, under Rule 12(b)(6), that a plaintiff state a claim upon which relief can be granted." *Wynder* v. *McMahon*, 360 F.3d 73, 80 (2d Cir. 2004). "A complaint could include a wealth of specific and particular facts, which would otherwise meet the standard for plausibility, but in some instances, no amount or combination of those facts could ever give rise to a violation of law." *Alharbi* v. *Miller*, 368 F. Supp. 3d 527, 560 (E.D.N.Y. 2019), *aff'd in part, dismissed in part*, 829 F. App'x 570 (2d Cir. 2020) (summary order). Therefore, "even when a complaint is sufficient to meet Rule 8(a)'s formal notice requirements, it will nonetheless be dismissed under Rule 12(b)(6) if the conduct alleged does not give rise to a violation of law." *In re Ditech Holding Corp.*, No. 19-10412 (JLG), 2023 WL 6798626, at *11 (Bankr. S.D.N.Y. Oct. 13, 2023).

3. The False Claims Act

The FCA, a federal statute "originally aimed … at stopping the massive frauds perpetrated by large contractors during the Civil War," *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 579 U.S. 176, 181 (2016), "imposes significant penalties on those who defraud the Government," *id.* at 180. And

although "Congress has repeatedly amended the Act, ... its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Id.* at 182. "A 'claim' includes direct requests to the government for payment as well as claims for reimbursement under federal benefits programs." *United States* v. *N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 286 (E.D.N.Y. 2016) (citation omitted). As relevant here, "a private person may bring a civil action" — known as a *qui tam* action — "on behalf of the government, as a 'relator,'" for violations of the FCA. *Id.* (citing 31 U.S.C. § 3730(b)).

The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To state a claim under this section, the relator must sufficiently plead that "[i] there was a false or fraudulent claim, [ii] [the defendant] knew it was false or fraudulent, [iii] [the defendant] presented the claim, or caused it to be presented, to the United States, and [iv] it did so to seek payment from the federal treasury." *United States ex rel. Pervez* v. *Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010).

Section 3729(a)(1)(B) of the FCA additionally imposes liability where a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Under subsection (a)(1)(B), the relator must allege that: "[i] [the defendant] made ... a false or fraudulent record or statement[,] [ii] [the defendant] knew it

to be false or fraudulent, and [iii] it was material to a claim. *Pervez*, 736 F. Supp. 2d at 811.

As is apparent, some elements are common to both causes of action. For example, in each case, there must have been a "claim." The FCA defines the term "claim," in pertinent part, as:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that — (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government — (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2). Either the claim itself, under subsection (a)(1)(A), or a record or statement material to that claim, under subsection (a)(1)(B), must have been false or fraudulent. And the defendant must have known that the claim or statement in question was false or fraudulent.

4. Pleading FCA Fraud Claims Under Federal Rule of Civil Procedure 9(b)

"The Rule 9(b) principles apply to complaints filed under the False Claims Act." *United States ex rel. Ladas* v. *Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016); *see also United States ex rel. Chorches for Bankr. Est. of Fabula* v. *Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) ("*Qui tam* complaints filed under the FCA, because they are claims of fraud, are subject to Rule 9(b)." (citing *Ladas*, 824 F.3d at 26)). Rule 9(b) provides that when "alleging fraud or

mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *Chorches*, 865 F.3d at 82. To satisfy this Rule, a complaint alleging fraud must "[i] specify the statements that the plaintiff contends were fraudulent, [ii] identify the speaker, [iii] state where and when the statements were made, and [iv] explain why the statements were fraudulent." *Shields* v. *Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994) (internal quotation marks omitted). The purpose of detailed pleadings under Rule 9(b) is "threefold — it is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Ladas*, 824 F.3d at 25-26 (quoting *O'Brien* v. *Nat'l Property Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)).

B. Analysis

The SAC alleges two discrete violations of the FCA — one under 31 U.S.C. § 3729(a)(1)(A) in Count I and one under 31 U.S.C. § 3729(a)(1)(B) in Count II — as well as violations of the False Claims Acts of twenty-six states, in Counts III to XXIX. The SAC generally argues that Defendants violated these statutes by (i) "failing to disclose" to medical providers that the Serter was only approved by the FDA as a single-patient use device (SAC ¶ 136); (ii) making false and misleading statements about reuse of the Serter on multiple patients (*id.*); (iii) instructing physicians and their clinical staff to reuse the Serter (*id.* ¶ 137); and (iv) establishing a system that encouraged customers to purchase

and use fewer Serters (*id.* ¶¶ 107-113). The Court addresses first Relator's federal FCA claims and then the state-law equivalents.[3]

1. Relator Fails to Allege a Violation of the FCA (Counts I and II)

To survive a motion to dismiss under Rule 9(b), a plaintiff asserting a violation of Section 3729(a)(1)(A) of the FCA must allege with particularity that: (i) the defendant submitted or caused the submission of a claim for payment to the government, (ii) the claim for payment itself was false or fraudulent, and (iii) the defendant knew the claim to be false or fraudulent. 31 U.S.C. § 3729(a)(1)(A). Section 3729(a)(1)(B) additionally imposes liability where a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B). Under subsection (a)(1)(B), the relator must allege that: "[i] [the defendant] made … a false or fraudulent record or statement[,] [ii] [the defendant] knew it to be false or fraudulent, and [iii] it was material to a claim. *Pervez*, 736 F. Supp. 2d at 811.

Defendants assert that Relator's claims fail on all fronts. Specifically, they argue that the SAC fails to allege with particularity that: (i) claims were submitted for federal reimbursement; (ii) the claims were factually or legally false; and (iii) Defendants caused the submission of false claims. Even

[3] In her brief in opposition to Defendants' motion to dismiss, Relator expressly withdraws her claims for violations of federal and state anti-kickback states. (*See* Pl. Opp. 23). Accordingly, the Court dismisses those claims. *See generally Anti-Monopoly, Inc.* v. *Hasbro, Inc.*, 958 F. Supp. 895, 907 n.11 (S.D.N.Y. 1997) ("[T]he failure to provide argument on a point at issue constitutes abandonment of the issue … which provides an independent basis for dismissal."), *aff'd*, 130 F.3d 1101 (2d Cir. 1997).

assuming *arguendo* that they caused the submission of false claims, Defendants assert that the SAC fails to allege that (iv) the practice of reusing Serters in providing patient care was material to government payment decisions or (v) Defendants acted knowingly or with reckless disregard. The Court considers each of these arguments in turn.

a. The SAC Fails to Allege the Submission of Claims to Government Healthcare Programs Adequately (Counts I and II)

As a threshold matter, Defendants assert that the SAC is deficient because it fails to sufficiently allege that claims — which concern treatments administering the iPro2 System with a Serter that has been reused on multiple patients without proper disinfection — were submitted to federal healthcare programs. (Def. Br. 10-16; Def. Reply 2-7). The Court agrees.

An FCA complaint must plead specific facts showing that a defendant submitted or caused the submission of a false or fraudulent claim to the government. *Chorches*, 865 F.3d at 83. It is well established that a complaint must not only include allegations of "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims," but also "actual false claims submitted to the government[.]" *United States ex rel. Polansky* v. *Pfizer, Inc.*, No. 04 Civ. 704 (ERK), 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009); *see also United States ex rel. Moore* v. *GlaxoSmithKline, LLC*, No. 06 Civ. 6047 (BMC), 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (stating FCA liability "cannot be adequately pleaded absent particularized allegations concerning the actual false claims submitted to the government"); *N. Adult*

Daily Health Care Ctr., 205 F. Supp. 3d at 288 (explaining that "allegations as to the existence of an overall fraudulent scheme do not plead fraud with particularity," and that FCA claims must also "allege the particulars of the false claims themselves"); *United States ex rel. Forcier* v. *Comput. Scis. Corp.*, 183 F. Supp. 3d 510, 520-21 (S.D.N.Y. 2016) (explaining the same).

Although the submission element often requires a plaintiff to "provide details of actual bills or invoices submitted to the government," *see Chorches*, 865 F.3d at 93, an FCA complaint can sometimes satisfy Rule 9(b)'s particularity requirement by making "plausible allegations" creating a "strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge," *id.* at 86; *see also Hagerty ex rel. United States* v. *Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016) (stating that a relator can meet the more accommodating standard "'by providing factual or statistical evidence to strengthen the inference of fraud *beyond possibility* without necessarily providing details as to each false claim'" (quoting *United States ex rel. Ge* v. *Takeda Pharm. Co.*, 737 F.3d 116, 123-24 (1st Cir. 2013) (emphasis in *Ge*))).

Of note, the relaxed standard "must not be mistaken for license to base claims of fraud on speculation and conclusory allegations." *Wexner* v. *First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990). Although the Second Circuit has yet to provide clear guidance as to what information plaintiffs must provide in order to plead false claims under this standard, sister circuits have generally

required the "specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made." *Hagerty*, 844 F.3d at 31-32 (internal quotation marks and citation omitted).

Relator concedes that she has not identified any actual false claims that were submitted to a government payor. (*See generally* SAC). Instead, Relator asserts that her allegations create a "strong inference" that such claims were indeed submitted. (Pl. Opp. 9).[4] To support her argument, Relator provides: (i) alleged statements from Medtronic personnel indicating that the company depended on customers reusing the Serter to enhance profitability (SAC ¶¶ 61-64); (ii) allegations that Medtronic encouraged customers and "trained healthcare providers … to reuse the Serter on multiple patients" (*id.* ¶ 82); (iii) Medtronic's purchasing system, which allowed purchase of Sensors and Serters separately, thereby promoting reuse (*id.* ¶ 108); (iv) acknowledgments from two Medtronic employees that clinicians reused Serters (*id.* ¶¶ 93, 98);

[4] It is not apparent to this Court that Relator is exempt from "the generally rigid requirement that fraud be pleaded with particularity." *Doe 1* v. *EviCore Healthcare MSI, LLC*, No. 22-530, 2023 WL 2249577, at *2 (2d Cir. Feb. 28, 2023) (summary order) (citation omitted). In *United States ex rel. Chorches for Bankruptcy Estate of Fabula* v. *American Medical Response, Inc.*, the Second Circuit held that, to plead under the more relaxed Rule 9(b) particularity standard, a "relator must make allegations that lead to a strong inference that specific claims were indeed submitted *and also* plead that the particulars of those claims were peculiarly within the opposing party's knowledge." 865 F.3d 71, 86 (2d Cir. 2017) (emphasis added). Here, Defendants are entities that manufacture and sell medical devices. Defendants do not submit claims for reimbursement. In other words, they are not "peculiarly" privy to the details required to be averred with particularity in a complaint in order to survive a motion — the who, what, where, why, or when of claims submitted to government payors. Accordingly, Relator has failed to plead that "the particulars of th[e] claims were peculiarly within [Defendants'] knowledge." *Id.* Nevertheless, for completeness, the Court will assess Relator's claims against the more flexible pleading standard contemplated in *Chorches*. 865 F.3d at 86.

(v) sales data that showed specific clinics with disproportionate Serter purchases compared to Sensors (*id.* ¶¶ 152-153); and (vi) marketing projections that demonstrated Medtronic's dominance in the CGM market during the relevant period (*id.* ¶¶ 146-147).

These allegations, taken individually or together, fail to support a "strong inference" of actual fraudulent submissions. To the contrary, these pleadings suffer from several notable deficiencies. To begin, generally absent from the pleadings is any link between the providers who purportedly received iPro2 System training from Defendants and any claims submitted as a result. For example, Relator asserts that Medtronic encouraged and trained individuals to reuse Serters on multiple patients (*see, e.g.*, SAC ¶¶ 80-82, 95), but fails to plead that these individuals (i) prescribed the iPro2 System to federal healthcare beneficiaries or sought reimbursement from federal healthcare programs; (ii) ever, in fact, reused Serters based on Defendants' advice (or used Serters at all when administering the iPro2 System);[5] or (iii) even if they did, sought reimbursements reflecting multi-patient Serter use (a non-FDA-approved use in the absence of proper disinfection), rather than single-patient Serter use (an FDA-approved use). Such attenuated line-drawing falls well

[5] Importantly, Serters are clearly designated as optional components of the iPro2 System. (*See* FDA Summary of Safety and Effectiveness Data at 3). Indeed, Relator has not pleaded any factual allegations that support the proposition that a Serter is required or even frequently used to administer the iPro2 System. (*See generally* SAC).

Relator's repeated description of a Serter as a "single-use" device is also misleading. (*See, e.g.*, Pl. Opp. 1). While the Serter is a single-*patient* device, it is not a single-*use* device — a distinction with significant meaning, especially when discussing the sale or purchase of more Sensors than Serters.

below the applicable Rule 9(b) standard. *See Hagerty*, 844 F.3d at 32 (affirming district court's dismissal of FCA claim because the complaint contained "no assertion that [defendant's] efforts actually resulted in patients scheduling, doctors performing, or government healthcare programs reimbursing the contemplated surgeries"); *see also United States ex rel. Kelly* v. *Novartis Pharms. Corp.*, 827 F.3d 5, 15 (1st Cir. 2016) (holding that relators failed to tie their allegations of misconduct to "specific fraudulent claims for payment"); *Ge*, 737 F.3d at 124 (rejecting a "*per se* rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed").

Indeed, noticeably absent from what is arguably Relator's most persuasive evidence — a list of fourteen healthcare providers who were "sold a high volume of Sensors with no corresponding Serters" during a six-month period in 2019-2020 and then billed the federal government for CGM services provided to Medicare beneficiaries — is an allegation that any of these providers sought reimbursements reflecting multi-patient Serter use as opposed to single-patient Serter use. (*See* SAC ¶¶ 152-153 (providing a table illustrating the number of Sensors each provider purchased during a six-month period)). The simple fact that certain providers purchased fewer Serters than Sensors is insufficient to create a strong inference that Serters were reused inappropriately, as use of a Serter is optional. Further, that fact offers limited insight into whether the reuse of Serters, if any occurred, was on multiple patients or the same individual; or whether, if used on multiple

patients, Serters were disinfected using the process that even Relator acknowledges made reuse safe (*i.e.*, by "soaking the Serter in a bleach solution"). (*Id.* ¶ 72). After all, given that the Sensor, unlike the Serter, is a single-*use* device (*i.e.*, unlike the Serter, can only be used once regardless of whether one or multiple patients are involved), it is unsurprising that some physicians would purchase more Sensors than Serters. *See United States ex rel. NPT Assocs.* v. *Lab'y Corp. of Am. Holdings*, No. 07 Civ. 5696 (ALC) (RLE), 2015 WL 7292774, at *6 (S.D.N.Y Nov. 17, 2015) (rejecting plaintiff's argument that court could infer submission of false claims based on, among other things, identification of five practice groups of physicians who allegedly sent government program business to defendant as a result of fraudulent scheme); *see also Hagerty*, 844 F.3d at 30, 32 (finding a list of sixteen hospitals that submitted claims to government payors for battery replacement was insufficient to compel an inference that the hospitals' reimbursement claims reflected battery replacements that were performed prematurely (and thus unnecessarily) at the defendant's encouragement).[6]

Relator's reliance on the testimony of two employees for the proposition that multi-patient reuse of Serters was widespread is equally unavailing. (*See,*

[6] For this same reason, the facts that Medtronic revised its purchasing system to allow customers to buy components separately, selling Sensors in boxes of five and Serters individually (SAC ¶¶ 107-113), or offered customer kits containing fewer Serters bundled with a higher number of Sensors (*id.* ¶ 110), fail to move the Rule 12(b)(6) needle. Similar to the allegations regarding unequal numbers of Serter and Sensor purchases made by some healthcare providers, Medtronic's purchasing system offers minimal insight into whether providers who purchased Serters, no matter how many or how few, reused those Serters on multiple patients based on Defendants' advice and submitted claims to federal healthcare programs reflecting that reuse.

e.g., SAC ¶ 93 (alleging that a sales representative estimated that 90% of her accounts "reused the Serter rather than discarding the component after each use")). These allegations either fail to plead that (i) Serters were reused on multiple patients, rather than on the same patient, and that this was done without proper disinfection or (ii) government healthcare programs reimbursed healthcare providers for those procedures. *See Hagerty*, 844 F.3d at 30, 32 (declining to infer that claims had been submitted despite plaintiff identifying a specific physician — with whom the defendant had communicated about premature battery replacement and who had replaced the battery in "several" patients — because plaintiff failed to allege that government healthcare program covered these patients or that any healthcare providers submitted claims for reimbursement on their behalf). Indeed, the SAC fails to identify or even ballpark "how many false claims these providers purportedly submitted or how [Medtronic's] actions caused their submission." *Id.* at 32.

Finally, Relator's reliance on data that (i) Medicare paid $46,000,000 based on the relevant CPT codes during the relevant time period and (ii) Medtronic controlled a majority of the CGM market is unpersuasive for several reasons. (Pl. Opp. 9-10). To begin, the reimbursement amount reflects all CGM devices reimbursed under CPT Codes 95250 and 95251, irrespective of manufacturer. Thus, it does not differentiate any payments for Medtronic's iPro2 System specifically. Indeed, by Relator's own admission, Medtronic's iPro2 System was not the only CGM on the market. The reimbursement figure is further attenuated from a plausible FCA claim because it includes

reimbursements under CPT Code 95251. Since CPT 95251 relates to data analysis services, not CGM equipment services, it has no relationship to a physician's use of a Serter, whether that use is new or reused. And even if the data were related to iPro2 System reimbursements, Medtronic's alleged share of the CGM market offers no insight into whether physicians comprising that market sought reimbursements reflecting, as is permissible, single-patient Serter use, multi-patient Serter use with proper disinfectant processes, or no Serter use at all, or as is impermissible, multi-patient Serter use with improper disinfectant processes. As have other courts, this Court rejects this amorphous theory of "market-share" causation as a means to satisfy Rule 9(b). *See, e.g.*, *NPT Assocs.*, 2015 WL 7292774, at *6 (dismissing FCA complaint, noting that "[a]sserting, for instance, that [defendant] annually received between $744 million and $1,053 billion in revenue from billing [g]overnment [p]rograms does not provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue" (internal quotation marks and citation omitted)); *see also United States ex rel. Osmose, Inc.* v. *Chemical Specialties, Inc.*, 994 F. Supp. 2d 353, 366 (W.D.N.Y. 2014) (dismissing plaintiff's "market-share theory" that defendant's significant share in a product market meant that government purchases must have been filled with defendant's product as "patently insufficient under both [the Second Circuit's] Rule 9(b) requirements and the more relaxed *qui tam* pleading standards of the other jurisdictions cited by [relator]"); *cf. Doe 1* v. *EviCore Healthcare MSI, LLC*, No. 22-530, 2023 WL 2249577, at *2 (2d Cir. Feb. 28,

2023) (summary order) (affirming district court finding that plaintiff who alleged that defendant had induced third parties to submit false claims for unnecessary medical services had failed to raise an inference that any claims actually were submitted by relying on "the volume of [defendant's business with claim-submitting entities]"); *Carrel* v. *AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1277 (11th Cir. 2018) (concluding that plaintiff cannot "rely on mathematical probability to conclude that [the defendant] surely must have submitted a false claim at some point").

In sum, viewed individually or in the aggregate, Relator's "evidence and arguments proceed more by insinuation than any factual or statistical evidence that would strengthen the inference" that Medtronic orchestrated the submission of fraudulent claims to government programs "beyond possibility." *Hagerty*, 844 F.3d at 33. This deficiency alone is fatal to Relator's federal FCA claims, and compels their dismissal.

b. The SAC Fails to Allege Falsity Adequately (Count I)

Even if the Court were to assume that Relator had sufficiently alleged the submission of claims for federal reimbursement, Count I would nevertheless be dismissed for the independent reason that the SAC fails to sufficiently allege that any submitted claims were false. (*See* Def. Br. 16-27).

As already noted, only false or fraudulent claims are actionable under the FCA. 31 U.S.C. § 3729(a)(1)(A)-(B). The falsity element of an FCA violation can be satisfied if the defendant presented, or caused others to present,

factually or legally false claims to the government. *Escobar*, 579 U.S. at 181. A plaintiff in an FCA action can establish falsity in one of three ways:

> [i] a factually false theory, under which a claim for payment is made to the government seeking payment for services that were never actually provided or for which the description of the goods or services provided is incorrect;
>
> [ii] an express false legal certification theory, where a claim for payment of federal funds falsely certifies compliance with a statute or regulation that must be complied with before payment can be made; and
>
> [iii] an implied false legal certification theory, where, although the claim for payment does not certify compliance with a statute or regulation on its face, compliance is a prerequisite to payment under the express statutory or regulatory terms.

United States ex rel. O'Toole v. *Cmty. Living Corp.*, No. 17 Civ. 4007 (KPF), 2020 WL 2512099, at *10 (S.D.N.Y. May 14, 2020) (citation omitted).

As a preliminary matter, it is the Court's understanding that the healthcare providers who used the iPro2 System did not seek reimbursement for the specific device (*e.g.*, the iPro2 System) or its components (*e.g.*, the Serter). Assuming government payors reimbursed practitioners, such reimbursements were for services provided and the general costs associated with physician-provided equipment, and Relator does not claim that those services were not provided or that the submitting providers otherwise inaccurately described their services. (*See generally* SAC). Therefore, reimbursement claims for services connected to a physician's use of the iPro2 System — whether with a new Serter, a reused Serter, or no Serter at all — are not "factually false."

Relator does not dispute this. Instead, the Court understands the SAC to rely on two variants of the "implied false certification theory." (Pl. Opp. 14). *First*, Relator argues that because the Serter, when used with multiple patients without proper disinfection, poses a risk of infection to patients, it fails to meet the medically "reasonable and necessary" standard for federal reimbursement. (SAC ¶ 4). *Second*, Relator asserts that the purported risk of infection posed by Defendants' recommended multi-patient Serter use rendered the iPro2 System in all instances "adulterated" and therefore ineligible for federal reimbursement. (*Id.* ¶ 124). The Court assesses each theory in turn.

i. Relator Fails to Allege That Procedures with Reused Serters Were Not Medically "Reasonable and Necessary"

Relator first asserts that services rendered by reusing Serters were not medically "reasonable and necessary" under the Medicare Act and, therefore, that any claims for those services were false under the FCA. (SAC ¶ 114 (citing 42 U.S.C. § 1395y(a)(1)(A)); Pl. Opp. 13-18). Specifically, Relator contends that the reuse of a Serter on multiple patients disinfected only with a CaviWipe fails to meet the "reasonable or necessary" standard for federal reimbursement because the increased risk of infection makes the procedure less safe than the alternative — performing the same procedure with a new Serter in accordance with the FDA label. (Pl. Opp. 15).

Section 1395y(a)(1)(A) of the Medicare Act states that "no payment may be made under [the Medicare statute] for any expenses incurred for items or services which ... are not *reasonable and necessary* for the diagnosis or

treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added). "[I]f a claim 'does not comply with statutory conditions for payment,' including that the items and services claimed are 'reasonable and necessary for the diagnosis and treatment of illness or injury,' as required by the Medicare statute, it is a false claim." *United States ex rel. Simpson* v. *Bayer Corp.*, 376 F. Supp. 3d 392, 400 (D.N.J. 2019) (first quoting *United States ex rel. Petratos* v. *Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017); then quoting 42 U.S.C. § 1395y(a)(1)(A)); *see also United States ex rel. Polukoff* v. *St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) (discussing "reasonable and necessary" standard).

"[A] device is not 'reasonable and necessary'" — and thus is not eligible for Medicare coverage — if it is (i) "not 'safe' and effective," (ii) "experimental," (iii) "not appropriate for the individual beneficiary's needs," or (iv) "substantially more costly than a medically appropriate and realistically feasible alternative pattern of care." *Dan Abrams Co. LLC* v. *Medtronic Inc.*, 850 F. App'x 508, 509 (9th Cir. 2021) (unpublished decision) (citing *Int'l Rehab. Sci. Inc.* v. *Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012)); *see also* MEDICARE PROGRAM INTEGRITY MANUAL § 13.5.43 (stating that Medicare will reimburse for reasonable and necessary items and services that are "safe and effective," "[n]ot experimental or investigational," and "[a]ppropriate"). Thus, "[a]n unsafe procedure is not reasonable and necessary." *United States* v. *Marshall Med. Ctr.*, No. 12 Civ. 98 (JAM), 2015 WL 2235461, at *11 (E.D. Cal. May 12, 2015); *cf. United States ex rel. Ruhe* v. *Masimo Corp.*, 929 F. Supp. 2d 1033, 1037 (C.D. Cal. 2012) ("The

use of a 'dangerously inaccurate' test would not be a reasonable and necessary procedure[.]").

However, "[m]erely showing that harm *can* occur is insufficient" to demonstrate a device is medically unsafe or ineffective. *Dan Abrams*, 850 F. App'x at 509 (emphasis in original). As the Centers for Medicare & Medicaid Services' guidance "makes clear," safety and efficacy determinations are based on "authoritative evidence" or "general[ ] accept[ance] in the medical community." *Id.* (citing *Sebelius*, 688 F.3d at 997).

Here, Relator's allegations regarding the potential harm that might ensue from a physician's reuse of a Serter after only disinfecting it with a CaviWipe are too speculative to serve as a basis to render any such claims submitted to Medicare legally false. For one, there are no allegations of any actual harms resulting from physicians' multi-patient use of Serters. (*See generally* SAC). Indeed, the SAC makes no attempt to identify any instance in which a physician, receiving Defendants' alleged recommendations regarding multi-patient use, followed those recommendations in a manner that actually created risk to their patient. *See United States* v. *Siemens Med. Sols. USA, Inc.*, No. 21 Civ. 1947 (MKB), 2023 WL 6050115, at *6 (E.D.N.Y. Sept. 14, 2023) (stating that the mere "presum[ption]" that the defendants' shipping practices created safety concerns, with no factual allegation that a patient actually suffered the presumed risk, was "fatal to [the] FCA claims").

In the absence of any factual allegations that a patient actually suffered or was exposed to the presumed risk, Relator also fails to provide any other

"authoritative evidence" — for example, FDA enforcement actions concerning Serter reuse or FDA Adverse Event Reports of patient infection — to plausibly allege that iPro2 Systems administered with a reused Serter were medically unsafe or ineffective. *Dan Abrams*, 850 F. App'x at 509. Indeed, the SAC does not cite to a single medical study, research paper, or publication indicating that a CGM system administered with a CaviWipe-disinfected Serter is medically unsafe or ineffective. *See, e.g.*, *id.* (affirming the district court's dismissal of an FCA claim, in part, because the relator "ma[de] no allegations about published studies demonstrating that [the device] is medically unsafe or ineffective"). Nor does Relator allege that such use is contrary to accepted standards of medical practice beyond citations to general FDA and Centers for Disease Control and Prevention ("CDC") guidelines that "recognize that grave harm can arise from the reuse of inadequately disinfected medical devices." (Pl. Opp. 16; *see, e.g.*, *id.* (stating that FDA guidance "cautions providers that, when devices are used on a patient, they 'become soiled and contaminated with microorganisms'"); *id.* at 17 (citing CDC guidance that "[a]dherence to infection prevention and control practices is essential to providing safe and high quality patient care")).[7] The Court finds references to these speculative, non-specific guidelines insufficient to demonstrate that the administration of the iPro2

[7] Relator's references to FDA guidelines regarding "single-use" devices (*see, e.g.*, Pl. Opp. 17), are particularly inapposite for reasons already noted *supra*, chiefly, that a Serter is not a single-use device. (*See* Serter User Guide at 10 (noting that one Serter can be used "for up to 600 sensor insertion uses" on a single patient, and setting forth instructions regarding cleaning the Serter after each use)).

System with a reused Serter is medically unsafe and unnecessary so as to warrant liability under the FCA.

In the absence of allegations of more "authoritative evidence" of non-speculative harm, Relator fails to sufficiently allege that reuse of the Serter would render the administration of the iPro2 System "not reasonable and necessary" under applicable regulations. *See Dan Abrams*, 850 F. App'x at 509-10 (rejecting relator's theory that the devices were not reasonable and necessary based on "anecdotal examples," explaining that "any surgery carries the potential risk of harm" and "[m]erely showing that harm can occur is insufficient" to demonstrate that a surgery or device is medically unsafe or ineffective); *see also Siemens Med. Sols.*, 2023 WL 6050115, at *6 (rejecting FCA claim made against a medical device company on the basis that defendants' shipping practices failed to comply with FDA-approved and FDA-cleared procedures, concluding that the complaint did not allege that "[d]efendants' shipping practices [actually] compromised any [medical device] for which claims to governments were actually submitted"), *appeal dismissed*, No. 23-7468, 2024 WL 1710898 (2d Cir. Feb. 5, 2024).[8]

[8] Relator's citations to *United States ex rel. Nargol* v. *DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), fail to aid her cause. (*See* Pl. Opp. 20-22). In *Nargol*, the "principal theory of fraud" advanced by the plaintiffs regarded a defectively manufactured hip-replacement product that "materially differed from the device the FDA approved," including by having nonconforming diametrical dimensions. *Nargol*, 865 F.3d at 37. After receiving FDA approval for the hip-replacement product, the defendants allegedly "palmed off a defective version" of the product "both directly on the government itself and on unsuspecting doctors and patients." *Id.* Here, there is no allegation that reused Serters were "defective" or in some other way a "materially deviant version" of the product approved by the FDA. Furthermore, *Nargol* emphasized the concealed nature of the defect, another fact that is notably absent from the instant case. *Id.*

ii. Relator's Allegations Regarding "Adulteration" Under the FDCA Fail

The allegations that multi-patient use of the Serter rendered the iPro2 System "adulterated" similarly fail to establish falsity. The FDCA prohibits the sale or manufacture of any device that is adulterated. 21 U.S.C. § 331(a). The FDCA states that a "[a] drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A). From this definition, Relator reasons that iPro2 Systems were "adulterated" under the FDCA because Medtronic recommended that the component Serters be used in an "insanitary condition" and while contaminated. (Pl. Opp. 19-20).

For starters, Relator's claims do not appear to satisfy the statutory definition of adulteration, as Relator does not assert that the "commodity itself" is deteriorating or contaminated, but rather that the manner in which the component Serter may be used poses "safety risks to consumers." *Nutritional Health All.* v. *Food & Drug Admin.*, 318 F.3d 92, 100-01 (2d Cir. 2003) (finding that the adulteration provisions of the FDCA "plainly concern the dangers of deterioration or contamination of the [product] itself, [and] not the unintended use (or misuse) of the product" (internal quotation marks omitted)). Indeed, a significant portion of the FDCA is concerned with definitions of different adulterated products, none of which clearly apply here. *See, e.g.*, 21 U.S.C. § 351(a)-(j).

In support of her argument, Relator relies on two criminal cases in which courts upheld convictions of healthcare practitioners for adulteration under the FDCA for reusing *single-use* devices during invasive medical procedures. (*See* Pl. Opp. 19-20 (citing *United States* v. *Kaplan*, 836 F.3d 1199, 1204, 1217-18 (9th Cir. 2016) (affirming a physician's conviction for adulteration because he reused a "single[-]use" plastic guide — which "c[a]me in distinctive packaging and [was] accompanied by a booklet clearly stating that [it was] sterile only for a single use" — during prostate biopsies) and *United States* v. *Jackson*, No. 5:21 Cr. 259-D (E.D.N.C. Mar. 28, 2023) (concerning similar conviction involving reuse of single-use device in balloon sinuplasty surgeries), *appeal pending*)). Even if these criminal convictions were applicable to the case at hand — and they are not — Relator's reliance on them would be misplaced, as the Serter is *not* a single-use device. (*See* SAC ¶ 58).

Further, even if reuse of a Serter rendered the iPro2 System "adulterated," it is not clear to the Court that adulteration, without more, renders a claim legally false. Indeed, some courts that have had the opportunity to consider whether FDCA violations are specifically actionable under the FCA have held that they are not. *See, e.g.*, *United States ex rel. Rostholder* v. *Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014) (explaining that the Medicare and Medicaid statutes do not expressly prohibit reimbursement for drugs that have been adulterated). In *Rostholder*, the relator alleged that the defendant had violated the FCA when it submitted claims for adulterated drugs. *Id.* In affirming dismissal of the relator's complaint, the Fourth Circuit

reasoned that "once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations." *Id.* at 701-02; *cf. United States ex rel. Crocano* v. *Trividia Health Inc.*, 615 F. Supp. 3d 1296, 1310-11 (S.D. Fla. 2022) (rejecting relator's attempt to equate a violation of FDA laws against misbranding with FCA violation, concluding that even if defendant's test strips were "misbranded and adulterated," relator had failed to cite any portion of the FDCA "closing the circuit between misbranding and claims for reimbursement from the government"); *but see United States ex rel. Campie* v. *Gilead Scis., Inc.*, 862 F.3d 890, 904 (9th Cir. 2017) (distinguishing *Rostholder* on the basis that there, relator alleged only regulatory violations, not a false claim). The Court finds that Relator has failed to allege that the iPro2 System was adulterated so as to render it ineligible for federal reimbursement.

c. Relator Fails to Allege Adequately That Defendants Made False Statements That Were Material (Count II)

Finally, in connection with Count II brought under 31 U.S.C. § 3729(a)(1)(B), Relator alleges that Defendants made "false statements" when encouraging providers to reuse the Serter. (SAC ¶ 136). Specifically, Relator asserts that Medtronic made false statements that were material to false claims submitted by physicians because Medtronic "fail[ed] to disclose to medical

providers … that the Serter was only approved by the FDA as a single use device." (*Id.*).

Liability can attach under the FCA if a defendant "knowingly … causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B); *see also Escobar*, 579 U.S. at 181 ("Liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."). False statements that are "integral to a causal chain leading to payment," may give rise to FCA liability. *United States ex rel. Main* v. *Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005).

Here, Relator asserts that Medtronic overtly encouraged providers to reuse the Serter or, "at minimum," made a materially misleading implication that the provider could do so safely, despite allegedly knowing it could not be effectively cleaned with an alcohol wipe or any other process short of an extended soak in bleach. (Pl. Opp. 24; *see, e.g.*, SAC ¶ 95 (alleging that Relator personally observed a Medtronic trainer instructing the medical staff of Medtronic's physician customers to reuse the Serter on multiple patients)). Even assuming *arguendo* that Relator presents sufficient allegations of false or misleading statements, however, Count II must be dismissed for the independent reason that Relator fails to sufficiently allege that physicians'

reuse of Serters, as allegedly promoted and encouraged by Defendants, was "material" to government payment decisions because Medicare and other payors would not have paid for services wherein patients were "needlessly expos[ed]" "to risk of harm." (SAC ¶¶ 114-129).

"[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 192. Thus, "[i]n addition to alleging a particular misrepresentation (including a potentially actionable omission), a plaintiff must … plead sufficient facts to plausibly allege that the misrepresentation is *material*." *United States ex rel. Yu* v. *Grifols USA, LLC*, No. 22-107, 2022 WL 7785044, at *2 (2d Cir. Oct. 14, 2022) (summary order) (emphasis in original) (citing *Foreman*, 19 F.4th at 109). The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court has made clear that the materiality requirement is a "demanding" one, and that plaintiffs must plead particular facts to support allegations of materiality. *See Escobar*, 579 U.S. at 194-95 n.6 (rejecting "assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment"); *Grabcheski* v. *Am. Int'l Grp., Inc.*, 687 F. App'x 84, 87 (2d Cir. 2017) (summary order) (noting that "[m]ateriality must be pleaded with particularity under Rule 9(b)").

In *Escobar*, the Supreme Court identified three factors relevant to the materiality assessment: "[i] whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; [ii] the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision; and [iii] whether the defendants' alleged noncompliance was 'minor or insubstantial.'" *Foreman*, 19 F.4th at 110 (citing *Escobar*, 579 U.S. at 194). In evaluating the final *Escobar* factor, courts "examine whether the defendants' alleged noncompliance was substantial." *United States* v. *Strock*, 982 F.3d 51, 65 (2d Cir. 2020). Materiality "cannot be found where noncompliance is minor or insubstantial," *Escobar*, 579 U.S. at 194, because material falsehoods are those that go to "the very essence of the bargain," *id.* at 193 n.5. These factors are considered holistically as "[n]o one factor is dispositive." *Foreman*, 19 F.4th at 110 (citation omitted).

Applying these factors, the Court finds that Relator has failed to allege a material misrepresentation sufficient to support an FCA claim. Here, Relator does not allege that (i) the government's decision to pay was expressly conditioned on single-patient use of the Serter, (ii) the government routinely refused to pay claims in such instances, or (iii) single-patient use of the Serter went to the "essence" of the providers' "bargain" with government payors. (*See generally* SAC). These failures render the SAC's materiality claims fatally deficient. *See, e.g.*, *Yu*, 2022 WL 7785044, at *3-5 (affirming dismissal of complaint where relators' claim that drug was "adulterated" because drug

failed to comply with current good manufacturing practices was not "material" for purposes of FCA claim); *see also Foreman*, 19 F.4th at 110-11 (finding fact that there were "no provisions in [a] contract or in the federal regulations specifically designating any of the contractual or regulatory requirements that [plaintiff] alleges [the defendant] violated as an express condition of payment," at most weighs "neutrally in the materiality analysis").

And, while medical necessity may be important to the government's payment decisions, for the reasons stated above, Relator has failed to sufficiently allege that reuse of the Serter would render the administration of the iPro2 System "medically unnecessary and unreasonable" under applicable regulations (*see supra* Section (1)(b)(i)) or "adulterated" (*see supra* Section (1)(b)(ii)). On this point, Relator's appeal to CDC and FDA infection-control guidelines stating that medical procedures should be safe and minimize the risk of infection is plainly insufficient to demonstrate materiality. As *Foreman* counsels, such "[g]eneric and routine appeals to the importance of … broad goals … do not put a contractor on notice of the importance of a given requirement to the government's payment decision, particularly where … the government has not expressly designated compliance with that requirement as a condition of payment." *Foreman*, 19 F.4th at 111, 117 (finding noncompliance insubstantial where, based on complaint allegations, it was "not apparent that [the noncompliance] affected [the defendant's] ability to provide … services" required under contract at issue); *see also United States ex rel. Yu* v. *Grifols USA, LLC*, No. 17 Civ. 2226 (GHW), 2021 WL 5827047, at *10

(S.D.N.Y. Dec. 8, 2021) (finding relator failed to sufficiently allege materiality, in part, because he did not plead that any of the alleged compliance violations "in fact, led to any … negative consequences," only that they "may lead" to contamination of equipment), *aff'd*, No. 22-107, 2022 WL 7785044 (2d Cir. Oct. 14, 2022) (summary order).

In conclusion, Relator fails to plausibly allege that any misrepresentation by Medtronic materially impacted any government healthcare program payment determinations. Accordingly, the Court also dismisses Count II of the SAC.[9]

2. The Court Declines to Exercise Supplemental Jurisdiction Over Relator's State-Law Claims

In addition to her federal claims, Relator alleges violations of the analogous False Claims Acts of the 26 named states. (Counts III to XXIX). Since Relator's FCA claims have been dismissed, there are no more federal claims remaining in this action.

A district court has discretion to "decline to exercise supplemental jurisdiction" after "dismiss[ing] all claims over which it has original jurisdiction." 28 U.S.C. § 1367(c); *see Klein & Co. Futures, Inc.* v. *Bd. of Trade of City of New York*, 464 F.3d 255, 263 (2d Cir. 2006) ("[T]he decision to retain jurisdiction is discretionary and not a litigant's right[.]"). In making this

[9] Because Relator must plead materiality to succeed on her claim, but has not done so, the Court need not consider the other elements required to state an FCA claim under 31 U.S.C. § 3729(a)(1)(A) or (B), *viz.*, whether Defendants caused the submission of false claims to federal healthcare programs (Def. Br. 27-28 (Count I)), and knowingly or recklessly engaged in a fraudulent scheme (*id.* at 30-31 (Counts I and II)).

determination, courts "balance[ ] the traditional 'values of judicial economy, convenience, fairness, and comity.'" *Kolari* v. *N.Y.-Presbyterian Hosp.*, 455 F.3d 118, 122 (2d Cir. 2006) (quoting *Carnegie-Mellon Univ.* v. *Cohill*, 484 U.S. 343, 350 (1988)). In general, "if the federal claims are dismissed before trial, … the state claims should be dismissed as well." *United Mine Workers of Am.* v. *Gibbs*, 383 U.S. 715, 726 (1966). Moreover, "[a]lthough the exercise of supplemental jurisdiction is discretionary, the ordinary case 'will point toward declining jurisdiction over the remaining state-law claims.'" *Jordan* v. *Chase Manhattan Bank*, 91 F. Supp. 3d 491, 511 (S.D.N.Y. 2015) (quoting *In re Merrill Lynch Ltd. P'ships Litig.*, 154 F.3d 56, 61 (2d Cir. 1998)).

The Second Circuit has deemed it proper to retain supplemental jurisdiction over state-law claims in limited circumstances — including actions that implicate preemption issues; state-law claims that remain when federal claims are voluntarily dismissed days before the scheduled start of trial; and in one instance where, by the time federal claims were dismissed, discovery had been completed, the court had decided three dispositive motions, and the case was ready for trial. *Valencia ex rel. Franco* v. *Lee*, 316 F.3d 299, 305-06 (2d Cir. 2003). Here, all factors weigh in favor of declining supplemental jurisdiction over Relator's state-law claims. There has been no discovery in this case; there have been no initial disclosures; no case management plan has been entered; no depositions have been taken; no expert discovery has been completed; and there is no trial date. Consequently, sending the pendent claims to state court would not result in the wasteful and duplicative

expenditure of resources. Further, the matter does not involve preemption issues. Accordingly, the Court declines to exercise supplemental jurisdiction over Relator's state-law claims. Those claims are dismissed without prejudice, and Relator is free to pursue them further in state court. *See Knight* v. *Standard Chartered Bank*, 531 F. Supp. 3d 755, 774 (S.D.N.Y. 2021) (declining to exercise supplemental jurisdiction over state law claims following dismissal of federal FCA retaliation claims).[10]

CONCLUSION

For the foregoing reasons, the Court GRANTS Defendants' motion to dismiss this action. The Clerk of Court is directed to terminate all pending motions, adjourn all remaining dates, and close this case.

SO ORDERED.

Dated: September 12, 2024
New York, New York

KATHERINE POLK FAILLA
United States District Judge

[10] In her opposition papers to the motion to dismiss, Relator seeks leave to add Medtronic Diabetes as a defendant. (Pl. Opp. 35). Given the Court's resolution of Defendants' motion, the Court denies Relator's motion as moot.